

## Message Text

UNCLASSIFIED

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ORIGIN HEW-06

INFO OCT-01 ARA-14 EUR-12 EA-09 NEA-10 ISO-00 OES-07

EB-07 COME-00 SIG-02 /068 R

DRAFTED BY DHEW/FDA: J. R. WEINROTH, M.D.:CCK

APPROVED BY OES/APT/BMP: WJWALSH, III

DHEW/PHS/OASH/OIH: RFISCHER

EUR/EX:CREDMAN (INFO)

EA/EX:JCUNNINGHAM (INFO)

ARA/EX:GCHAFIN (INFO)

NEA?EX:EABINGTON (INFO)

-----129855 292013Z /63

P R 291825Z JUN 77

FM SECSTATE WASHDC

TO AMEMBASSY BERN PRIORITY

AMEMBASSY COPENHAGEN PRIORITY

AMEMBASSY LONDON PRIORITY

AMEMBASSY THE HAGUE PRIORITY

AMEMBASSY AMMAN PRIORITY

AMEMBASSY MEXICO PRIORITY

AMEMBASSY BOGOTA PRIORITY

AMCONSUL RIO DE JANEIRO PRIORITY

AMEMBASSY TOKYO PRIORITY

AMEMBASSY CANBERRA PRIORITY

AMEMBASSY WELLINGTON PRIORITY

AMEMBASSY SINGAPORE PRIORITY

AMEMBASSY REYKJAVIK PRIORITY

AMEMBASSY ATHENS PRIORITY

AMEMBASSY VIENNA PRIORITY

AMCONSUL MILAN PRIORITY

AMEMBASSY PARIS PRIORITY

AMEMBASSY ANKARA PRIORITY

AMEMBASSY BONN PRIORITY

AMEMBASSY HELSINKI PRIORITY

AMEMBASSY STOCKHOLM PRIORITY

AMEMBASSY MADRID PRIORITY

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AMEMBASSY TEL AVIV PRIORITY

AMEMBASSY TEHRAN PRIORITY

INFO AMEMBASSY BRASILIA

AMEMBASSY ROME

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E.O. 11652: N/A

TAGS: OGEN, ETRD, EIND, TBIO, XB, XF,XG, XU

SUBJECT: FDA ADVISORY - POTENTIAL FOR FAILURE OF MEDICAL DEVICE("RECALL" T-II8-7)

1. FDA ADVISES OF THE FOLLOWING "RECALL":

PRODUCT INVOLVED:

"BENNETT MODEL AO-1 AIR-OXYGEN MIXER". PRODUCT IS USED TO DELIVER A SPECIFIED AIR/OXYGEN MIXTURE (FROM 21-100 PERCENT OXYGEN).

PRODUCT IDENTIFICATION:

THE PRODUCT IS LABELED: "BENNETT AO-1 AIR-OXYGEN MIXTURE".

MANUFACTURER: BENNETT RESPIRATORY PRODUCTS, INC., SANTA MONICA, CALIFORNIA.

RECALLING FIRM: PURITAN-BENNETT CORPORATION, OAK AT 13TH STREET, KANSAS CITY, MISSOURI 64106.

2. REASON FOR RECALL RECOMMENDATION:

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THE FIRM'S OPERATING INSTRUCTIONS FOR THIS PRODUCT STATE "CAUTION: WET COMPRESSED AIR MAY DAMAGE THE MIXER". IF MOISTURE DAMAGE OCCURS, SOME OF THE FIRM'S ORIGINAL "AIR REGULATOR SEAT MECHANISMS" JUST INSIDE THE AIR INTAKE POINT HAVE FAILED, THUS ALLOWING AIR TO FLOW INTO THE OXYGEN SIDE OF THE MIXER. THIS COULD RESULT IN A PATIENT (INCLUDING INFANTS IN INCUBATORS) GETTING A REDUCED AMOUNT OF OXYGEN (OTHER THAN THAT INDICATED ON THE MIXER). THUS, A PATIENT COULD POTENTIALLY GET STRAIGHT AIR AND NO OXYGEN (OTHER THAN THAT NORMALLY IN AIR).

3. POSTS ARE REQUESTED TO CONTACT FOREIGN CONSIGNEES TO DETERMINE IF THEY HAVE RECEIVED THE FIRM'S LETTER DATED 25 APRIL, 1977 WHICH IN ADDITION TO DEFINING THE PROBLEM SUMMARIZES A VARIETY OF INSTRUCTIONS WHICH USERS SHOULD ADHERE TO PRIOR TO UTILIZING THIS DEVICE. ANY QUESTIONS CONSIGNEES MAY HAVE REGARDING THIS ADVISORY SHOULD BE DIRECTED TO MR. J. J. WATERS, VICE PRESIDENT, REGULATORY AFFAIRS, PURITAN-BENNETT CORPORATION, KANSAS CITY, MO 64106.

4. FOREIGN CONSIGNEES AS FOLLOWS:

ING. RUEGGE AG  
AUSTRASSE 19  
CH-5430 WETTINGEN  
SWITZERLAND

SIMONSEN AND WEELS  
EFTF A/S  
14 ROSKILDEVEJ  
ALBERTSLUND, DENMARK

SIMONSEN AND WEEL LTD  
HATHERLY HOUSE  
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HATHERLY ROAD  
SIDCUP DA14 4BR  
KENT, U.K.

STOPLER INSTRUMENTEN AND  
APPARATEN N.V.  
P O BOX 2445  
UTRECHT, HOLLAND

TAREQ SCIENTIFIC BUREAU  
P O BOX 463  
AMMAN, JORDAN

ESTABLECIMIENTOS  
MEXICANOS COLLIERE SA  
APARTADO NO. 114 BIS  
MEXICO 22, D.F.

INSTITUTO ROOSEVELT  
APTDO AEREO 35 35  
BOTOTA, COLOMBIA

SOCIEDADE COMERCIAL PRO  
MEDICO LTDA  
RUA ITAPIRU 1292  
RIO DE JANEIRO, BRAZIL

AMCO INCORPORATED  
8-7-4-CHOME IIDABASHI  
CHIYODA-KU  
TOKYO, JAPAN

MEDISHIELD DIVISION  
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COMMONWEALTH INDUSTRIAL GASES  
P O BOX 81 BUNDOORA  
SETTLEMENT RD BUNDOORA  
VIC AUSTRALIA 3083

NEW ZEALAND INDUSTRIAL  
GASES LTD  
P O BOX 30-337  
LOWER HUTT, NEW ZEALAND

SINGAPORE OXYGEN AIR  
LIQUIDE PTE LTD  
P O BOX 24I  
16 JALAN BUROH JURONG  
SINGAPORE 22

AUSTURBAKKI H F  
P O BOX 1282  
REYKJAVIK, ICELAND

PHARMACEUTICAL CO. LTD. MOHSEN SHALTCHILAR AND BROS.CO.  
OMONIA SQUARE NORTH VILLA AVE  
ATHENS, GREECE NO. 130

COMESA  
SPITALGASSE  
VIENNA IX AUSTRIA

COMESA S.P.A.  
VIA FOGAZZARO 36  
20135 MILAN  
ITALY

COMPAGNIE FRANCAISE DE  
PRODUITS OXYGENES  
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154 RUE DE L UNIVERSITE  
75007 PARIS FRANCE

KAZIM DEDEOGLU  
SIRKECI DOGUBANK  
IS HANI N.D. 113  
ISTANBUL, TURKEY

CARL A. HOYER  
PARIALLEE 44  
28 BREMEN 1, GERMANY

INSTRUMENTARIUM OY  
PL 357  
00101 HELSINKI 10  
FINLAND

LANDSTIGENS  
INKIPS CENTRAL  
S-171 83 SOLNA  
STOCKHOLM, SWEDEN

MEDICINA Y ODONTOLOGIA  
JOAQUIN GARCIA MORATO  
133-TRIP  
MADRID 3, SPAIN

MINISTRY OF HEALTH SUPPLY DIV.  
STATE OF ISRAEL  
P O B 7094  
TEL-AVIV, ISRAEL VANCE

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NNN

## Message Attributes

**Automatic Decaptoning:** X  
**Capture Date:** 01-Jan-1994 12:00:00 am  
**Channel Indicators:** n/a  
**Current Classification:** UNCLASSIFIED  
**Concepts:** MEDICAL EQUIPMENT, RECALLS  
**Control Number:** n/a  
**Copy:** SINGLE  
**Sent Date:** 29-Jun-1977 12:00:00 am  
**Decaption Date:** 01-Jan-1960 12:00:00 am  
**Decaption Note:**  
**Disposition Action:** n/a  
**Disposition Approved on Date:**  
**Disposition Case Number:** n/a  
**Disposition Comment:**  
**Disposition Date:** 01-Jan-1960 12:00:00 am  
**Disposition Event:**  
**Disposition History:** n/a  
**Disposition Reason:**  
**Disposition Remarks:**  
**Document Number:** 1977STATE151377  
**Document Source:** CORE  
**Document Unique ID:** 00  
**Drafter:** J. R. WEINROTH, M.D.:CCK  
**Enclosure:** n/a  
**Executive Order:** N/A  
**Errors:** N/A  
**Expiration:**  
**Film Number:** D770232-0893  
**Format:** TEL  
**From:** STATE  
**Handling Restrictions:** n/a  
**Image Path:**  
**ISecure:** 1  
**Legacy Key:** link1977/newtext/t1977066/aaaaafew.tel  
**Line Count:** 247  
**Litigation Code IDs:**  
**Litigation Codes:**  
**Litigation History:**  
**Locator:** TEXT ON-LINE, ON MICROFILM  
**Message ID:** bbd6417d-c288-dd11-92da-001cc4696bcc  
**Office:** ORIGIN HEW  
**Original Classification:** UNCLASSIFIED  
**Original Handling Restrictions:** n/a  
**Original Previous Classification:** n/a  
**Original Previous Handling Restrictions:** n/a  
**Page Count:** 5  
**Previous Channel Indicators:** n/a  
**Previous Classification:** n/a  
**Previous Handling Restrictions:** n/a  
**Reference:** n/a  
**Retention:** 0  
**Review Action:** RELEASED, APPROVED  
**Review Content Flags:**  
**Review Date:** 19-Oct-2004 12:00:00 am  
**Review Event:**  
**Review Exemptions:** n/a  
**Review Media Identifier:**  
**Review Release Date:** n/a  
**Review Release Event:** n/a  
**Review Transfer Date:**  
**Review Withdrawn Fields:** n/a  
**SAS ID:** 2162208  
**Secure:** OPEN  
**Status:** NATIVE  
**Subject:** FDA ADVISORY - POTENTIAL FOR FAILURE OF MEDICAL DEVICE("RECALL" T-II8-7)  
**TAGS:** OGEN, ETRD, EIND, TBIO, XB, XF, XG, XU, FDA  
**To:** BERN COPENHAGEN MULTIPLE  
**Type:** TE  
**vdkvgwkey:** odbc://SAS/SAS.dbo.SAS\_Docs/bbd6417d-c288-dd11-92da-001cc4696bcc  
**Review Markings:**  
Margaret P. Grafeld  
Declassified/Released  
US Department of State  
EO Systematic Review  
22 May 2009  
**Markings:** Margaret P. Grafeld Declassified/Released US Department of State EO Systematic Review 22 May 2009